

## REMARKS

The requisite fee of \$1,115.00 for a five-month extension of time may be charged to Deposit Account No. 02-1818. Any fees that may be due in connection with the filing of this paper or with this application may be charged to Deposit Account No. 02-1818. If a Petition for Extension of Time is needed, this paper is to be considered such Petition.

Claims 1-18 and 34-39 are pending. Claims 19-33, which are directed to non-elected subject matter, are cancelled herein without prejudice or disclaimer. Applicant expressly reserves the right to file divisional/continuation application(s) to the cancelled and any unclaimed subject matter. Claim 1 is amended to correct antecedent basis of terms recited therein. For example, the recitation "sodium ions" in parts (ii) and (iv) of claim 1 is amended to recite "sodium salt," antecedent basis for which is found in part (i) of the claim, which recites "at least one water-soluble sodium salt." The recitation "magnesium ions" in part (iv) of claim 1 is amended to recite "magnesium salt," antecedent basis for which is found in part (iv) of claim 1, which recites "at least one water-soluble magnesium salt." Claim 3 is amended to correct a typographical error. Claims 12, 13, 35 and 36 are amended to correct grammatical errors. Basis for the amendment of claims 35 and 36 can be found, *e.g.*, at page 6, lines 33-22. Basis for new claim 37 can be found, *e.g.*, at page 7, lines 31-32. Basis for new claim 38 can be found, *e.g.*, at page 9, lines 1-2. Basis for new claim 39 can be found, *e.g.*, at page 9, lines 9-12. No new matter is added.

## TRAVERSAL OF RESTRICTION REQUIREMENT

### Traverse of finding of lack of unity

The Office Action restricts the pending claims into ten groups as follows:

- Group I: claims 1-9, drawn to a composition for use in a purgative;
- Group II: claims 10-11, drawn to a method of inducing purgation of the colon;
- Group III: claims 12-13, 18 and 36, drawn to methods of treatment or prevention of one or more of the listed conditions;
- Group IV: claims 14-15, drawn to a method for the treatment or prevention of acute gastrointestinal infections;
- Group V: claims 16-17, drawn to a method for the treatment or prevention of constipation;
- Group VI: claims 19-21, drawn to a composition for the use in a purgative;
- Group VII: claims 22-23, drawn to a method of inducing purgation of the colon;
- Group VIII: claims 24-25 and 30-35, drawn to a method for the treatment or prevention of one or more of the listed conditions in the absence of diathermy;
- Group IX: claims 26-27, drawn to a method for the treatment or prevention of acute gastrointestinal infections; and
- Group X: claims 28-29, drawn to a method for the treatment or prevention of constipation.

The Examiner, recognizing that the rules of unity of invention under PCT Rule 13.1 apply to the instant case, urges that there is a lack of unity because the ten groups allegedly do not relate to a single inventive concept. This conclusion is based upon the premise that a special technical feature between the groups is disclosed in Kang *et al.* (US Pat. 4,186,025, issued January 29, 1980). The Examiner alleges that the common technical feature among the claims is a composition that includes (i) at least one water soluble sodium salt; (ii) at least one water soluble minimally degradable sugar; (iii) at least one water soluble potassium salt; and (iv) at least one water soluble magnesium salt. The Office Action alleges that the claims of Groups I - IV lack unity of invention because the composition of claim 1 allegedly is not novel. The Examiner alleges that Kang *et al.* (U.S. Pat. No. 4,186,025) discloses a fermentation medium that includes a hydrolyzed starch, a source of magnesium ions, a source of phosphorous, a source of nitrogen and water, and therefore destroys novelty of the compositions of claims 1 and 19 and unity of invention amongst groups I-X.

Reconsideration of the Requirement respectfully is requested in view of the following remarks. The composition of claim 1, as discussed below, is novel over the cited art, rendering it a novel technical feature shared among all pending claims. Therefore, all pending claims are unified.

#### **The Claims**

Claim 1 of Group 1 recites:

*A composition for use in a purgative, the composition comprising:*

- (i) at least one water-soluble sodium salt;*
- (ii) at least one water-soluble minimally degradable sugar in an amount, by weight, of from about 1 to about 3 times the weight of sodium salt in the composition;*
- (iii) at least one water-soluble potassium salt in an amount, by weight, of from about 0.05 to about 1 times the weight of the sodium salt in the composition; and*
- (iv) at least one water-soluble magnesium salt, wherein the weight of magnesium salt in the composition is from about 0.1 to about 10 times the weight of sodium salt in the composition.*

The claims of Group II are directed to methods of inducing purgation of the colon using a composition of claims of Group I.

The claims of Group III are directed to methods of treatment or prevention of lavage-associated hyponatremia, hypoosmolality, nausea, malaise, vomiting, headache, convulsions using a composition of claims of Group I and methods of pre-colonoscopy or pre-surgical lavage using a composition of claims of Group I.

The claims of Group IV are directed to methods for the treatment or prevention of acute gastrointestinal infections using a composition of claims of Group I.

The claims of Group V are directed to methods for the treatment or prevention of constipation using a composition of claims of Group I.

Hence, the composition of claim 1 is a technical feature shared among all pending claims. As discussed below, the composition of claim 1 is novel over the cited art. Therefore, all pending claims are unified.

#### **Disclosure of the Cited Art**

Kang *et al.* discloses a fermentation medium that contains a carbon source, a source of magnesium ions, a source of phosphorous, a source of nitrogen and water. Kang *et al.* discloses a fermentation medium (E-1 medium) that contains 5 grams of potassium acid phosphate, 0.1 gram of magnesium sulfate, ammonium nitrate, Promosoy 100 (an enzymatic digest of soybean meal), 30 grams of hydrolyzed starch and 1 liter of tap water (see col. 2, lines 42-48). Kang *et al.* discloses a nutrient broth medium that contains 0.3% by weight of beef extract and 0.5% by weight of peptone in distilled water (col. 3, lines 29-32). Kang *et al.* also discloses including 5% or 7% by weight sodium chloride in the nutrient broth medium (col. 4, lines 57-63). Kang *et al.* describes a basal medium including 0.5% by weight of a carbon source selected from among arabinose, cellobiose, fructose, galactose, glucose, inositol, lactose, maltose, mannitol, mannose, raffinose, rhamnose, ribose, salicin, sucrose, trehalose, xylose, dextrin, adonitol, dulcitol, inulin, sodium alginate and starch (col. 5, lines 1-40). Kang *et al.* discloses a medium that includes an oligosaccharide containing from about 3 to about 10 monomer units at a concentration of about 1 to about 5% by weight (col. 8, lines 12-20), a source of magnesium ions in the medium in a range from about 0.005 to about 0.02% by weight (col. 8, lines 21-30), and a buffer salt, such as a potassium phosphate or a sodium phosphate salt, at a concentration from about 0.4% to about 0.6% by weight (col. 8, lines 35-41). Kang *et al.* discloses that potassium hydroxide or another suitable base, such as sodium hydroxide, may be added to control pH (col. 8, line 67 through col. 9, line 2). Kang *et al.* discloses a fermentation medium containing E-1 medium and glucose, hydrolyzed starch, sucrose, dextrin or maltose or combinations thereof (Example 1).

Kang *et al.* does not disclose any composition that includes at least one water-soluble sodium salt; at least one water-soluble minimally degradable sugar in an amount, by weight, of from about 1 to about 3 times the weight of sodium salt in the composition; at least one water-soluble potassium salt in an amount, by weight, of from about 0.05 to about 1 times the weight

of the sodium salt in the composition; and at least one water-soluble magnesium salt, where the weight of magnesium salt in the composition is from about 0.1 to about 10 times the weight of sodium salt in the composition.

### Analysis

A common underlying technical feature among the claims of Groups I-V is a composition that includes (i) at least one water-soluble sodium salt; (ii) at least one water-soluble minimally degradable sugar in an amount, by weight, of from about 1 to about 3 times the weight of sodium salt in the composition; (iii) at least one water-soluble potassium salt in an amount, by weight, of from about 0.05 to about 1 times the weight of the sodium salt in the composition; and (iv) at least one water-soluble magnesium salt, where the weight of magnesium salt in the composition is from about 0.1 to about 10 times the weight of sodium salt in the composition. In order for Kang *et al.* to destroy unity among Groups I-V, Kang *et al.* must disclose all of these features.

In setting forth the lack of unity rejection, the Examiner did not consider the limitations of claim 1 that recite that the amount of minimally degradable sugar, potassium salt and magnesium salt in the composition is based on the weight of the sodium salt in the composition. Because these elements define the composition, they must be considered.

The instant specification defines a "minimally degradable sugar" as a carbohydrate moiety that is substantially resistant to endogenous digestion in the gastrointestinal tract (see page 7, lines 28-30). Exemplary minimally degradable sugars include xylose, xylotriose, xylooligosaccharides, fructu-oligosaccharides, fructosans and galactooligosaccharides (*e.g.*, see page 7, lines 31-34).

Kang *et al.* discloses a number of fermentation media, none of which includes at least one water-soluble sodium salt; at least one water-soluble minimally degradable sugar in an amount, by weight, of from about 1 to about 3 times the weight of sodium salt in the composition; at least one water-soluble potassium salt in an amount, by weight, of from about 0.05 to about 1 times the weight of the sodium salt in the composition; and at least one water-soluble magnesium salt, where the weight of magnesium salt in the composition is from about 0.1 to about 10 times the weight of sodium salt in the composition.

For example, Kang *et al.* discloses an E-1 fermentation medium that contains 0.5% potassium acid phosphate, 0.01% magnesium sulfate, ammonium nitrate, Promosoy and 3% hydrolyzed starch. It is well known in the art that hydrolyzed starches are rapidly digested in the gastrointestinal tract (*e.g.*, see US Pat. No. 6,774,111, col. 7, lines 52-63). Hence, the E-1

medium does not contain a minimally degradable sugar. In addition, the E-1 medium does not include a sodium salt. Thus, the E-1 medium of Kang *et al.* does not include every element of the composition of claim 1.

Kang *et al.* also describes a modified nutrient broth containing 5% or 7% by weight NaCl, beef extract and peptone in distilled water. This modified nutrient broth does not contain a potassium salt, a magnesium salt or a minimally degradable sugar. Thus, the modified nutrient broth medium of Kang *et al.* does not include every element of the composition of claim 1.

Kang *et al.* also describes a medium that includes an oligosaccharide containing from about 3 to about 10 monomer units, such as a hydrolyzed starch, at a concentration of about 1 to about 5% by weight; about 0.005 to about 0.02% by weight of a magnesium salt; about 0.4 to about 0.6% by weight of a sodium or potassium salt of phosphoric acid, such as  $\text{KH}_2\text{PO}_4$ ,  $\text{K}_2\text{HPO}_4$ ,  $\text{K}_3\text{PO}_4$ ,  $\text{NaH}_2\text{PO}_4$ ,  $\text{Na}_2\text{HPO}_4$  or  $\text{Na}_3\text{PO}_4$  and an organic or inorganic nitrogen source. As discussed above, hydrolyzed starch is not a minimally degradable sugar. Hence, this medium does not include a minimally degradable sugar. In addition the ratios among the ingredients are not within the scope of the claims. For example, the amount of sugar (5%) is 10-12.5 times the amount of sodium salt (0.4-0.5%), not 1-3 times the amount of sodium salt as instantly claimed. The amount of magnesium salt (0.005%-0.02%) is 0.0125-0.05 times the amount of sodium salt, not 0.1-10 times the amount of sodium salt as instantly claimed. Thus, this medium of Kang *et al.* does not include every element of the composition of claim 1.

Kang *et al.* mentions a "basal medium" at col. 5. The "basal medium" is described in Kang *et al.* as "the basal medium described by D.W. Dye, New Zealand Journal of Science, Vol. 5, pages 393-416 (1962)" (see col. 5, lines 1-4). Kang *et al.* does not disclose the composition of the "basal medium" other than that it contains 0.5% of a carbon source. The carbon sources disclosed in Kang *et al.* used in the "basal medium" are selected from among arabinose, cellobiose, fructose, galactose, glucose, inositol, lactose, maltose, mannitol, mannose, raffinose, rhamnose, ribose, salicin, sucrose, trehalose, xylose, dextrin, adonitol, dulcitol, inulin, sodium alginate and starch. Kang *et al.* does not disclose a ratio of from 1:1 to 3:1 of sugar to sodium salt in its basal medium. Kang *et al.* does not disclose any ratios among the components of the basal medium. Thus, the basal medium of Kang *et al.* does not include every element of the composition of claim 1.

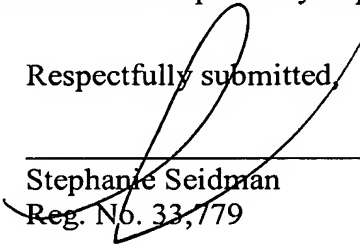
None of the media compositions disclosed in Kang *et al.*, such as E-1 medium, modified nutrient broth, the medium described at cols. 8-9, or basal medium, includes at least one water-

soluble sodium salt; at least one water-soluble minimally degradable sugar in an amount, by weight, of from about 1 to about 3 times the weight of sodium salt in the composition; at least one water-soluble potassium salt in an amount, by weight, of from about 0.05 to about 1 times the weight of the sodium salt in the composition; and at least one water-soluble magnesium salt, where the weight of magnesium salt in the composition is from about 0.1 to about 10 times the weight of sodium salt in the composition. Thus, Kang *et al.* does not disclose any composition that includes every element of the composition of claim 1 and therefore does not anticipate the composition of claim 1. Hence, Kang *et al.* does not destroy novelty of the composition of claim 1. The composition of claim 1 is a technical feature shared among all claims of Groups I-V. Thus, Groups I-V (claims 1-18 and 34-36) possess unity. Therefore, the claims of Groups II-V should be rejoined with the claims of Group I and examined in this application.

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In view of the election, amendments and remarks herein, withdrawal of the restriction requirement, examination on the merits and allowance are respectfully requested.

Respectfully submitted,

  
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